



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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3739

In re Application of:

	S.D. Augustine	)	Group No.:	3739
Serial No.:	09/771,791	)	Examiner:	R. D. Gibson
Filed:	January 29, 2001	)	Docket No.	AUGA17000025
For:	<b>SURGICAL BARRIER DEVICE INCORPORATING AN INFLATABLE THERMAL BLANKET WITH A SURGICAL DRAPE TO PROVIDE THERMAL CONTROL AND SURGICAL ACCESS</b>			

CERTIFICATION UNDER 37 CFR § 1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on November 10, 2003, in an envelope addressed to: Mail Stop AF, Box 1450, Commissioner for Patents, Alexandria VA 22313-1450

March 17, 2004  
Date

Terence A. Meador  
Signature

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REPLY BRIEF

In response to the Examiner's Answer mailed January 29, 2004, the applicant submits this Reply Brief.

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## ARGUMENT

The overriding issue in this appeal is straightforward: has the Examiner established that the cited art includes all of the elements of the rejected claims?

### **Anticipation Rejection: Claims 58, 59, 61, 63, 69, and 70**

To anticipate a claim, a reference must teach every element of the claim.

Claim 58, which is representative, recites a combination for use during surgery on a person, which comprises:

“a flexible base sheet;

a material sheet attached to a first surface of the base sheet by a plurality of seals to form an inflatable portion with a periphery, the inflatable portion having a periphery;

a plurality of apertures through the base sheet within the periphery; and

*a surgical drape attached to, or formed integrally with, the inflatable portion.”*

(Italics added for emphasis).

It is the Examiner's burden to establish that Augustine et al. teaches every element of claim 58, including “a surgical drape”. If Augustine et al. omits any element, it is the Examiner's burden to establish that the missing element is inherent in the reference. Augustine et al. includes every element of this claim except the last: “a surgical drape attached to, or formed integrally with, the inflatable portion.” No reference to a “surgical drape” can be found in Augustine. In fact, Augustine omits this element.

The contention in the Examiner's Answer is that “the drape of the present invention and the drape of Augustine et al are formed of the same materials, i. e. heat sealable plastic, and *can* perform the same functions. Both drapes help retain heat and both *can* be used as a sterile covering to prevent the transportation of microorganisms. Thus the foot drape of Augustine et al *can* be clearly classified as a surgical drape.” Examiner's Answer page 3, paragraph (11). (Italics added for emphasis.)

If by “*can*” the Examiner means “are able”, the applicant respectfully submits that the Examiner has not shown how a “foot drape” at the end of a thermal blanket that traps and retains heat around a patient's feet and protects them from burns “*can*” function as a surgical drape. The Examiner's argument is that they are made from the same materials; therefore they “*can*” have the same function. This is speculation. How can a foot drape positioned at the end of a thermal blanket and hanging over feet constitute, or function as, a surgical drape, even if made from the same materials as a surgical drape? Where is surgery to be performed using the foot drape? How is surgery to be performed using

the foot drape? What aseptic field is formed by a foot drape at the end of a thermal blanket? Augustine et al. does not answer these questions. Neither does the Examiner. The Examiner's speculation does not establish the inherency of a "surgical drape" in Augustine et al.

To establish inherency, the Examiner has the burden to show, by extrinsic evidence, that the omitted "surgical drape" is *necessarily present* in the thermal blanket described by Augustine et al., *Schering Corp. v Geneva Pharmaceuticals, et al.*, 339 F3d 1373 (Fed. Cir. 2003). According to *Schering*, one way to establish inherency of an invention in a patent is to later discover that the invention is produced in its entirety by a thing described and claimed in the patent. That is not the case here. The Examiner has introduced no evidence that any foot drape formed at the end of any thermal blanket constructed according to Augustine et al. has functioned or been used as a "surgical drape."

For extrinsic evidence, the Examiner relies solely on the Mahidal University article to establish that "the foot drape of Augustine et al. can be clearly classified as a surgical drape." In other words, it must be the Examiner's contention that the Mahidal article establishes that the surgical drape is *necessarily present* in the thermal blanket of Augustine et al. But that is not the case. The sole relationship that the Mahidal University article has to the invention of the rejected claims is to establish that the term "surgical drape" has a particular meaning in the medical arts, thereby distinguishing it from a foot drape. According to the article, a "surgical drape" is "used to form an aseptic field". It does not explain how a foot drape at the end of a thermal blanket establishes an aseptic field. The Examiner simply says that this is so ("The foot drape of Augustine et al is a sterile covering that will prevent the transport of microorganisms."), with absolutely no evidence or reasoning in support of this conclusion.

In fact, the Mahidal article does not establish that a surgical drape is necessarily present in the thermal blanket with a foot drape of Augustine et al. After defining a surgical drape, the article states why conventional ones are inadequate to the special needs in developing countries in performing Caesarian surgery on HIV-positive patients. Special embodiments of surgical drapes are described; none traps air; none is attached to a thermal blanket; none is used with convective thermal treatment during surgery.

**Accordingly, the Examiner has not established by extrinsic evidence that a "surgical drape" is necessarily present in the thermal blanket described by Augustine et al. and the applicant requests the Board to allow these claims.**

**Obviousness Rejections: Claims 60,62, 64-67, 68, 75-86, 88, and 93-95**

*Prima facie*, rejection of a claim for obviousness over a combination of references requires motivation to make the combination, reasonable expectation of success, and the inclusion of all elements of the rejected claim in the combination.

The portion of the Argument in the Appeal Brief which goes to obviousness analyzes and responds to the obviousness rejection in the Final Action. It establishes that the rejection for obviousness fails the *Graham* tests and does not meet the requirements for *prima facie* obviousness.

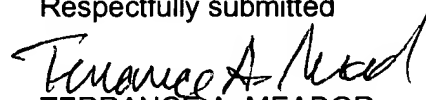
Only the claims rejected for obviousness are considered in the traversal of the obviousness rejection. Claim 58, which is rejected only for anticipation, is not discussed in that traversal. Yet the Examiner's Reply discusses "provision of access to a surgical site through the drape," noting that claim 58 fails to recite any opening in the surgical drape, and stating that this limitation is not recited until claim 60 (which depends from claim 58 through claim 59). The thrust of this argument, at least as it goes to claim 58, is not clear to the applicant. The applicant's statements regarding access to a surgical site are directed to the claims rejected for obviousness, which include claim 60. No mention of claim 58 can be found in this section of the Appeal Brief.

**In no other respect has the Examiner responded to the traversal of the Final rejection for obviousness. Accordingly, the applicant respectfully requests the Board to allow these claims.**

### SUMMARY

For the reasons given in the Appeal Brief and in this paper, and for other good reasons of record in the file of this application, all of the claims remaining in this application are patentably distinct from the references of record, alone or in combination. The Board is therefore respectfully requested to reverse the rejections for anticipation and obviousness and direct that this application be allowed.

Respectfully submitted

  
TERRANCE A. MEADOR  
Reg. No. 30, 298

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INCAPLAW  
1050 Rosecrans Street, Suite K  
San Diego, CA 92106

Telephone: (619) 222-2531 Fax: (619) 222-2327